

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on day of January, 2004

Dianna Swarringin

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

KERSHMAN et al. Attorney Docket No. 45100-8802301

Serial No. 10/706,241 Group Art Unit: Not Yet Assigned

Filed: November 12, 2003 Examiner: Not Yet Assigned

For: ORAL TESTOSTERONE DELIVERY SYSTEM WITH

IMPROVED SUSTAINED RELEASE

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER §1.97 (e) (1)

This Information Disclosure Statement (IDS) is being filed within three months of the filing date of the application or before the mailing date of any office action on the merits.

Applicant submits herewith patents, publications or other information of which they are aware, if any, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose.

The filing of this IDS shall not be construed as a representation that a search has been made an admission that the information cited is, or is considered to be, material to patentability or that no other material information exists.

The filing of this IDS shall not be construed as an admission against interest in any manner. Any such patents, publications or other possibly material information which are known to Applicants are listed on the enclosed copy of PTO Form 1449 (modified) listing documents,

legible copies of which are enclosed. After reasonable inquiry, no other information material to examination of the above-referenced application is known to Applicant.

Examination on the merits is requested accordingly. If Examiner believes there is any issue which could be readily resolved or other action could be taken to advance this application, such as Examiner's amendment, it is requested that Examiner please telephone the undersigned.

Any necessary fee in this matter is authorized to be charged to Deposit Account 07-1985

Respectfully submitted,

Date: /28-04

Linda L. Lewis, Reg. 31,212

Greensfelder, Hemker & Gale, P.C.

Intellectual Property Group

10 South Broadway, Suite 2000

St. Louis, Missouri 63102-1774

(314) 241-9090

Attorneys For Applicants

Attachments:

PTO/SB/08B Cited references (6) Postal acknowledgement card

PTO/SB/08B (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substante for form 1449/PTO Complete if Known **Application Number** 10/706,241 Filing Date INFORMATION DISCLOSURE November 12, 2003 STATEMENT BY APPLICANT First Named Inventor KERSHMAN, Alvin Art Unit Not Yet Assigned (Use as many sheets as necessary) **Examiner Name** Not Yet Assigned Attorney Docket Number Sheet 45100-8802301 of

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	PETER J. SNYDER, Androgens, The Pharmacological Basics of Therapeutics, 10th ed., pages 1635-1648, Goodman and Gilman	
	2	SVEND G. JOHNSEN, EDGAR P. BENNETT, V. GUANO JENSEN, Therapeutic Effectiveness of Oral Testosterone, The Lancet, December 21, 1974, pages 1473-1475.	
	3	MARIE FOGH, CHARLES S. CORKER, HELEN McLEAN, IVAN BRUUNSHUUS PETERSEN, JOHN PHILIP AND NIELS E. SKAKKEBAK,	
		Serum-Testosterone During Oral Administration of Testosterone in Hypogonadal Men and Transsexual Women, ACTE Endocrinologica, 1978, pages 643-649	
	4	P.R. DAGGETT, M.J. WHEELER AND J.D.N. NABARRO, Oral Testosterone, a Reappraisal, 1978, pages 121-129	
	5	E. NIESCHLAG, H.J. CUPPERS & E.J. WICKINGS, Influence of sex, testicular development and liver function on the bioavailability of oral testosterone,	
		European Journal of Clinical Investigation, 1977, pages 145-147.	
	6	H. FREY, A. AAKVAAG, D. SAANUM AND J. FALCH, Bioavailability of Oral Testosterone in Males, European Journal of Clinical Pharmacology, 1979, pages 345-349	
а	-		

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.